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10/822,303	04/09/2004	Rino Rappuoli	20480.019	3584
27476 7590 02/22/2010 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097				
EXAMINER				
PENG, BO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,303

Applicant(s)

RAPPUOLI ET AL.

Examiner

BO PENG

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 121-132 is/are pending in the application.
- 4a) Of the above claim(s) 121-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 127-132 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: attachments

DETAILED ACTION

1. This Office action is in response to the amendment filed on July 13, 2009. Claims 9-21, 24, 29-93, 99-113, 116, 118-120 have been cancelled. New Claims 127-132 have been added. Claims 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 121-132 are pending. Claims 121 and 123-126 were withdrawn as non-elected. Claim 122 has been withdrawn by Applicant on February 23, 2009. Accordingly, Claims 1-8, 22, 23, 25-28, 94-98, 114, 115, 117 and 127-132 are considered in this Office action. The claims are examined to the extent of the elected S polypeptide SEQ ID NO: 6042, and second S1 fragment SEQ ID NO: 7307, and adjuvant MF59 (see Applicants' election filed on May 14, 2008).

The priority date of SEQ ID NOs: 6042 and 7307

2. In the Remarks filed on February 23, 2009, and July 13, 2009, Applicant has indicated that the elected SEQ ID NO:6042 was disclosed as SEQ ID NO:147 in the provisional application 60/463,109, filed on April 14, 2003. A review of 60/463, 109 shows the description of SEQ ID NO: 147, and a sequence alignment shows that SEQ ID NO:147 is identical to SEQ ID NO:6042. Therefore the priority date of SEQ ID NO:6042 has been determined as **April 14, 2003**.

3. In the reply filed on July 13, 2009, Applicant has further identified that SEQ ID NO: 7307, which consists of residues 14-662 of SEQ ID NO: 147, was disclosed in the provisional 60/468,312, filed May 22, 2003, see specifically on page 140. A review of 60/473,144 (not 60/468, 312), filed May 22, 2003, shows the description of residues 14-662 of SEQ ID NO: 147. The sequence analysis shows that SEQ ID NO: 7307 is identical to amino acids 14-662 of SEQ

ID NO: 147. Therefore the priority date of SEQ ID NO: 7307 has been determined as **May 22, 2003**.

Specification

4. **(Prior objection-withdrawn)** The objection to the specification, for containing an embedded hyperlink and/or other form of browser-executable code, **is withdrawn** in view of the amendment to the specification, filed on July 13, 2009.
5. **(Prior objection-withdrawn)** The objection to the specification for use of trademarks, has been noted in this application is withdrawn in view of the amendment to the specification filed on July 12, 2009.

Claim Objection

6. **(Prior objection-withdrawn)** The objection to Claims 96 for the term “a transdomain region” **is withdrawn** in view of the amendment to the claim.
7. The objection to Claim 122 for depending on a withdrawn claim is moot in view of withdrawn of Claim 122 in the reply filed on July 13, 2009.

Claim Rejections - 35 USC § 101 Utility

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. **(Prior rejection-withdrawn)** The rejection of Claims 94-98 under 35 U.S.C. 101, for being directed to non-statutory subject matter, is withdrawn in view of the amendment to the

claims.

Claim Rejections - 35 USC § 112, first paragraph-Scope of Enablement

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior rejection-maintained)** The rejection of Claims 22, 23, 25-28, 114, 115 and 117 under 35 U.S.C. 112, first paragraph, for failing to comply with the scope of enablement requirement, **is maintained** for the reason of record.

In response to Applicant's arguments:

12. Applicant asserts that (1) Weiss recognizes that the mouse model is art-recognized for SARS vaccine research. (2) Nothing in Stockman and Cavanagh references suggests that Applicant's claims are not enabled.

13. Applicant's arguments have been considered, but found not persuasive. Regarding Applicant's argument (1), Weiss indicates that, although some animals, such as mice, are used for experimental testing, there are no animal models available for study of SARS because none of them reproduce the SARS-induced disease observed in humans. Animal models to study the efficacy of SARS vaccines are not available (Microbiol Mol Biol Rev. 2005; 69(4):635-64. Para 4, right col. p. 653).

14. Regarding Applicant's argument (2), the Stockman and Cavanagh references are cited for assessing the state of prior art and predictability in the art at the time the application was filed, but are not for suggesting whether or not Applicant's claims are not enabled as applicant

asserted. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). In the present case, the scope of the claims encompasses prophylactic and therapeutic use of SARS S polypeptides, particularly S polypeptide of SARS Tor2 strain (S_{Tor2}), for treating or preventing SARS caused by any SARS-CoV in a subject, including humans. However, the state of the art has indicated that the instant claimed invention is highly unpredictable because a vaccine for a new virus is not routinely achievable. At the time the invention was made, a new class of human coronaviruses was just identified as the etiological agent of SARS. A few SARS-CoV strains, such as Tor2, Urbani, CHHK-W1 and HKU-39849 isolates, were just isolated and their genomes were just characterized (Marra, *Science* 300(5624):1399-404, 2003, cited in IDS; and Rota, *Science* 300:1394-1399, 2003, cited in IDS). However, the molecular biology and pathogenesis of SARS-HCoV were largely unknown. Importantly, the prior art indicates that no drug or treatment has been proven to be effective for control of SARS (Stockman 2006, *PLoS Med* 3(9):e343). No any vaccine against SARS was available. Thus, one of skill in the art was not in possession of knowledge of treating and preventing SARS at the time the claimed SARS vaccine was made. Therefore, it is unpredictable in the art whether or not the claimed vaccine comprising comprising S_{Tor2} peptides could protect or inhibit other strains of SARS-HCoV, thus treating or preventing all SARS-HCoV infections in a subject as claimed.

15. The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working

examples in the specification (see MPEP 2164.05(a) [R-2]). *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the specification has not shown whether or not the claimed vaccine comprising S polypeptide SEQ ID NO: 6042 or SEQ ID NO:7307 could induce protective immunity in any animal models against SARS infection caused by SARS tor2 strain, or other SARS-HcoV strains, nor whether not the claimed vaccine can be used for treating SARS infection. As a result, the specification, at the time the application was filed, the specification does not enable one skilled in the art to use the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. **(Prior rejection-withdrawn in part-maintained in part)** The rejection of Claims 1, 3-8, 22, 27, 28 and 94 are rejected under 35 U.S.C. 102(e) as being anticipated by Plummer (US20070258999, Provisional application 60/465783, Effective filing date April 28, 2003), as evidenced by Dimitrov (US2006/0240515A1), **is withdrawn** in view of Applicant's argument.

Applicants claim priority of SEQ ID NO: 6042 to U.S. provisional application No. 60/463109, filed April 14, 2003. Applicant argues that SEQ ID NO:147 in Application No. 60/463109 discloses the identical sequence to SEQ ID NO:6042. Plummer is therefore not prior art to SEQ ID NO:6042. This argument has been found persuasive. The rejection of Claims 1, 3-8, 22, 27, 28 and 94 is therefore withdrawn.

18. The rejection of Claims 2 and 23, which is directed to a sequence comprising SEQ ID NO:7307, is **maintained** for the reason of record. The priority of Claim 2 has been determined as May 22, 2003 in Para 3 above. Thus, Plummer is proper prior art to a polypeptide comprising SEQ ID NO:7307. The rejection is therefore maintained.

102/103 REJECTION

19. (**New rejection**) Claims 1-8, 22, 23, 27, 28 and 94 are rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over GenBank **AY274119** (submitted on April 13, 2003; see Attachment (1) to the Office action; The draft of AY274119 was publicly available on April 12, 2003 as evidenced by the website “SARS-associated Coronavirus”(see Attachment (2) to this Office action); as evidenced by Plummer (US20070258999) and Dimitrov (US2006/0240515A1).

20. Claims 1-8, 22, 23, 27, 28 and 94 read on an isolated polypeptide, or a vaccine, comprising a SARS coronavirus Spike (S) polypeptide SEQ ID NO:6042, or a fragment S1 SEQ ID NO:7307, wherein the polypeptide is in oligomeric form, wherein the oligomer is a trimer, wherein the polypeptide comprising an immunogenic, surface-exposed fragment of the amino acid sequence SEQ ID NO: 6042, wherein the polypeptide is a fusion peptide comprising S

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protein SEQ ID NO: 6042.

21. GenBank AY274119 discloses a S polypeptide of SARS coronavirus Tor2 strain (S_{Tor2}), which is 100% identical to the claimed polypeptide SEQ ID NO: 6042, as evidenced by the sequence alignment, see Attachment (3) to this Office action. The website “SARS-associated Coronavirus” is cited as evidenced that sequence data of whole genome of Tor2 similar to AY274119 was publicly available on April 12, 2003.

22. It is noted that Applicant’s provisional application 60/463,109, filed on April 14, 2003, has indicated that the draft genome sequence of Tor2 is attached as FIGURE 301, see Para 1, p.2. 60/463,109 has also indicated: “the Centers for Disease Control has published on their website (<http://www.cdc.gov/ncidod/sars/pdf/nucleoseq.pdf>) a nucleotide sequence of a SARS-CoV strain (attached as FIGURE 501). The CDC has also published a phylogenetic tree of the predicted N, S and M proteins (attached as FIGURE 502). This tree places the SARS virus outside any of the previously known coronavirus groups”; see p.2.

23. Although AY274119 does not explicitly teach that S polypeptide is a fusion protein, S_{Tor2} polypeptide is a fusion polypeptide comprising a S1 domain and a S2 domain, as evidenced by Plummer. S1 domain of S polypeptide comprises an amino acid sequence 100% identical the claimed S1 fragment SEQ ID NO:7307, and also comprises a surface-exposed fragment of the claimed amino acid sequence SEQ ID NO: 6042. Although AY274119 does not explicitly teach that S polypeptide is a trimer (claim 5), S polypeptide can form a trimer, as evidenced by Dimitrov. Dimitrov teaches that like viral envelope glycoproteins of class I fusion proteins, the full-length membrane-associated S polypeptide and some soluble peptides thereof are trimeric through the transmembrane domain (Para [0204] and [0207]).

24. In view of AY274119 and the specification of provisional application 60/463109, the claimed polypeptide comprising SARS S polypeptide of SEQ ID NO:6042, or SEQ ID NO:7307, appears to be same as or equivalent to S protein disclosed in AY274119.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. **(Prior rejection-withdrawn)** The rejection of Claims 95-98 under 35 U.S.C. 103(a) as being unpatentable over Plummer (US20070258999), as applied to Claim 94 above, in view of Cavanagh D et al (J Gen Virol. 1986 Jul;67:1435-42), is **withdrawn** in view of Applicant's argument.

27. **(Prior rejection-withdrawn)** The rejection of Claims 25, 26, 114, 115 and 117 under 35 U.S.C. 103(a) as being unpatentable over Plummer (US 20070258999), as applied to Claim 22 above, in view of Gasparini *et al.* (European Journal of Epidemiology 17:135-140, 2001), is withdrawn.

28. Applicant traverses both 103 rejections on the ground that SEQ ID NO:147 in Application No. 60/463109, filed on April 14, 2003, discloses the identical sequence to SEQ ID NO:6042. Plummer is therefore not prior art to SEQ ID NO:6042. This argument has been found

persuasive. The rejections are therefore withdrawn. However, a new ground(s) of rejection is made below.

29. **(New rejection)** Claims 25, 26, 95-98, 114, 117 and 127-132 are rejected over GenBank AY274119, as applied to Claims 1, 22 and 94 above, further in view of Ksiazek, et al. (N Engl J Med. 2003 May 15;348(20):1953-66. Epub 2003 Apr 10), Cavanagh et al (J Gen Virol. 1986; 67:1435-42; cited in previous Office action); and Song, et al. (J Gen Virol. 1998;79 (Pt 4):719-23)

30. Claims 95-98 and 127-132 are directed to the polypeptide of Claims 1, 22 and 94, wherein said fragment does not include the last 50 or 70 amino acids of the C-terminus of SEQ ID NO: 6042, wherein said fragment does not include a transdomain region of SEQ ID NO: 6042, wherein said fragment does not include a C-terminus cytoplasmic domain of SEQ ID NO: 6042, and wherein said fragment does not include a N-terminus signal sequence. **Claims 25, 26, 114 and 115** are directed to a vaccine of Claim 22 further comprising an adjuvant, wherein the adjuvant is MF59. **Claim 117** is directed to a method of vaccinating a subject comprising administering to the subject a vaccine of Claim 22.

31. The relevance of AY274119 is set forth in Para 21-24 *supra*.

32. AY274119 does not explicitly teach S_{Tor2} peptide fragments, which do not include the last 50 or 70 amino acids of the C-terminus of SEQ ID NO: 6042; or an N-signal peptide and/or a C-terminal transmembrane domain. AY274119 does not teach use of MF59 as a vaccine adjuvant, or a method of vaccinating a subject using the S peptide of Claim 22.

33. Ksiazek teaches a novel SARS-coronavirus, which is identified as the etiologic agent for

the outbreak of SARS in humans, see e.g. Abstract. SARS virus is closely related to animal coronaviruses, such as avian IBV (infectious bronchitis virus), see e.g. Fig.3, p.1959. Ksiazek indicates that there is a need to develop strategies, especially strategies for developing vaccines, to control newly emerged SARS virus, see e.g. Para 1, right col. p. 1964.

34. Cavanagh teaches a polypeptide of S1 subunit of S protein from IBV (a coronavirus), which does not include the amino acids corresponding to “the last 50 or 70 amino acids of the C-terminus of SEQ ID NO: 6042”, and does not include “a C-terminal transmembrane domain”, See e.g. *Introduction*, Para 1, p. 1435. Cavanagh also teaches a method preventing coronavirus infection using the S1 polypeptide and adjuvant, see Para 1, p.1436. Cavanagh shows that the S1 subunit is the major inducer of virus neutralizing antibodies (Whole document, particularly p.1440-1442). Vaccination of chickens with the S1 subunit was able to induce virus-neutralizing antibodies, but virus that lacked the S1 subunit was unable to induce neutralizing antibody (Title, pp. 1439-1442).

35. Song teaches a recombinant S1 (rS1) glycoprotein of IBV; see e.g. Abstract, and Fig.1. Song also teaches a method of preventing coronavirus infection using rS1 polypeptide and adjuvant, see e.g. Para 3, right col. p.720. Song teaches the expressed rS1 glycoprotein alone can induce a protective immune response as well as an antibody response; see e.g. Abstract.

36. Gasparini teaches MF59 adjuvant, see e.g. Abstract. Gasparini teaches that a subunit influenza vaccine with adjuvant MF59 is more immunogenic. Statistical analysis showed that more subjects developed enhanced immunogenicity who received subunit influenza vaccine with adjuvant MF59 than those who received conventional subunit influenza antigens without MF59 (p. 137).

37. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make the claimed S fragments as a vaccine candidate. In the case of *KSR International Co. v. Teleflex Inc.* (82 U.S.P.Q. 2d1385, 2007), the Supreme Court provided a number of bases on which a claimed invention may be found obvious. In particular, “When there is a design need or market pressure to solve a problem and there are a finite number of identified predictable potential solutions, a person of ordinary skill has good reason to pursue the known potential options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense”. In the present case, first, the prior art indicates that there is a known need/desire in the art to develop make a vaccine to control newly emerged human SARS coronavirus, as shown by Ksiazek. Secondly, the prior art has provided a finite number of identified predictable potential solutions for making the claimed S1 fragments of S protein as a vaccine candidate. Specifically, AY274119 has provided full sequence of SARS genome, including the sequence of S protein. Ksiazek has taught one of ordinary skill in the art that newly emerged SARS-coronavirus is closely related to animal coronaviruses, such as avian IBV (infectious bronchitis virus), see e.g. Fig.3, p.1959. Both Cavanagh and Song have provided teachings indicating that S1 fragments are critical and sufficient to induce virus-neutralizing antibodies and protective immunity against animal coronaviruses. Finally, the prior art shows that those of ordinary skill in the art were able to pursue the known potential options with a reasonable expectation of success in making/using the specific S 1 fragments. For instance, one of ordinary skill in the art was capable of acquiring analogue art or related knowledge from known animal coronaviruses as shown by Ksiazek. One of ordinary skill in the art was also capable of making S1 fragment using routine lab practice,

and testing the S1 polypeptide in animals, as shown by Song. Thus, one skilled in the art would have a reasonable expectation of success in making and using the claimed S1 fragments of SARS for inducing immune response, given that the sequence of S gene was available at the time the application was filed, and also given the success of the prior art that the S1 fragment is sufficient to induce immune response as shown by both Cavanagh and Song. In other words, making or using different S1 fragments as claimed are design choice since they are considered as functional equivalents. One skilled in the art would also have a reasonable expectation of success in using adjuvant MF59, given that MF59 can enhance immunogenicity of subunit peptide antigens, as taught by Gasparini. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Remarks

38. No claim is allowed.
39. The following reference is made of record and considered pertinent to applicant's disclosure. The reference appears not to be a prior art because it was disclosed on April 14, 2003, which is the same day as the filing date of the instant provisional application 60/463,109.

Press Release by CDC, on April 14, 2003: "CDC Lab Sequences Genome of New Coronavirus"; see Attachment (4) to this office action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648